Big Sky Diagnostic Imaging, LLC: FDA Safety Communication

FDA MedWatch Safety Alert

The FDA became aware of problems associated with the quality of mammograms performed at Big Sky Diagnostic Imaging, LLC, located in Butte, Montana. The FDA worked with the American College of Radiology (ACR) as it performed a routine review of a sample of mammograms performed by Big Sky Diagnostic Imaging, LLC that included images taken between November 20, 2011 and November 20, 2013. Results from that review included poor quality mammograms. The FDA will continue to monitor this issue and keep the public informed as new information becomes available.

This does not mean that the results of the examinations were inaccurate, but it does mean that patients should speak to their health care providers about whether their mammograms need to be repeated.

Additional Information:

Big Sky Diagnostic Imaging, LLC in Butte, Montana: FDA Safety Communication. FDA MedWatch Safety Alert. June 23, 2014.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm402253.htm

ConvaTec, Inc., Flexi-Seal CONTROL Fecal Management System Kit: Class I Recall

FDA MedWatch Safety Alert

No 510k application was submitted to FDA for this device. In addition, ConvaTec received reports from U.S. healthcare facilities of 13 adverse events including twelve serious injuries and one death for the period February 2013 through March 2014. The Auto-Valve feature that is unique to the Flexi-Seal CONTROL Fecal Management System Kit has not consistently performed relative to the inflation and deflation of the device's retention balloon. Use of this device may lead to: rectal damage (necrosis/ perforation/ulceration or bleeding); expulsion of the device and/or leakage; fecal soiling of bed linen/incontinence pads leading to skin deterioration around the anus, peeling skin, and raw, irritated lesions due to skin contact with fecal matter; and death.

Additional Information:

ConvaTec, Inc., Flexi-Seal CONTROL Fecal Management System Kit: Class I Recall - Not Cleared for Marketing. FDA MedWatch Safety Alert. June 20, 2014.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm402172.htm

HydroFinity Hydrophilic Guidewires by NDC/Covidien: Recall

FDA MedWatch Safety Alert

NDC issued a recall of all HydroFinity Hydrophilic Guidewires due to two reports of the outer polymer jacket to the core wire being damaged when the guidewire was withdrawn rapidly through certain delivery catheters and ten cases where the product was less severely damaged during use. Damage to the jacket can result in embolization of polymer, potentially leading to vessel occlusion or damage. Vessel occlusion may necessitate surgical intervention to resolve.

Additional Information:

HydroFinity Hydrophilic Guidewires by NDC/Covidien: Recall. FDA MedWatch Safety Alert. June 20, 2014.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm402006.htm

Smiths Medical Portex Low Dead Space Connector with Sideport, 3.5mm: Class I Recall

FDA MedWatch Safety Alert

FDA notified health professionals of a class 1 recall of this product due to one lot of 3.0mm sized connectors, Lot #2553426, which were mislabeled in packages as 3.5mm. The affected products were distributed in November 2013. On April 10, 2014, Smiths Medical sent an Urgent Medical Device Recall to all affected customers. Customers should examine their inventory, remove all affected products and returned the completed Response Form and affected products to Smith Medical.

Additional Information:

Smiths Medical Portex Low Dead Space Connector with Sideport, 3.5mm: Class I Recall. FDA MedWatch Safety Alert. June 13, 2014.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm401038.htm

Advocate Redi-Code+ Blood Glucose Test Strips by Diabetic Supply of Suncoast: Recall

FDA MedWatch Safety Alert

Diabetic Supply of Suncoast, Inc. initiated a nationwide voluntary recall of all BMB-BA006A Advocate Redi-Code+ blood glucose test strip lots manufactured by BroadMaster Bio-Tech Corp due to a labeling error which could result in confusion about which meter models the Redi-

Code+ BMB-BA006A blood glucose test strips are designed to be used with. In the incorrect labeling, the test strips model (BMB-BA006A) was omitted. Suncoast is recalling the test strips in an effort to avoid confusion and the possible misuse of the Advocate Redi-Code+blood glucose test strips with the Taidoc meters listed in the Firm Press Release, which could result in incorrect glucose results.

Additional Information:

Advocate Redi-Code+ Blood Glucose Test Strips by Diabetic Supply of Suncoast: Recall. FDA MedWatch Safety Alert. June 11, 2014.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm400668.htm

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Discussions with Healthcare Providers

Ortho-Phthalaldehyde (OPA): Small Sample Survey Summary

Survey Topic: Ortho-Phthalaldehyde (OPA) - Survey Final Report
Year Conducted: 2014

Introduction

Reusable medical devices are devices that health care providers can reprocess and reuse to diagnose and treat multiple patients, for example, surgical forceps, endoscopes and stethoscopes. Reusable devices can be grouped into one of three categories according to the degree of risk of infection associated with the use of the device: critical (highest risk), semi-critical, and non-critical devices (lowest risk) . Semi-critical devices are those that contact intact mucous membranes or non-intact skin, such as endoscopes. Semi-critical devices are designed and labeled for multiple uses and are reprocessed by thorough cleaning and high-level disinfection or, if feasible, by sterilization. Ortho-phthalaldehyde (OPA) is one such high-level disinfectant.

The FDA conducted a small sample survey with clinicians and other health care providers to learn about users' experiences with OPA in the hospital setting. The survey questions focused specifically on disinfecting and rinsing processes, training and instructions for use, and patient/staff reactions that may be related to the use of OPA. Information from the survey is intended to help FDA obtain a better understanding of users' perspectives and any issues of concerns that may be present in the clinical environment.

Methodology

A small sample of health care providers from hospitals that participate in FDA's Medical Product Safety Network (MedSun) were queried to obtain detailed perspectives about the use of

OPA. Respondents from nine different hospitals (located in the West, Northeast, Mid-Atlantic, and Southern regions of the U.S.) participated in the voluntary survey.

Six hospitals involved in the survey have over 500 beds and three hospitals have between 100-500 beds. All selected respondents have experience with OPA disinfectant in various clinical areas of the hospital.

The respondent sample included health care providers from Risk Management/Legal, Clinical Education, Nursing and Nurse Management, Quality Assurance, Industrial Hygiene, Infection and Prevention Control, Purchasing, Speech Pathology, Central Sterile Processing, and the Endoscopy Department.

Overview of Responses

Devices Disinfected with OPA

Nearly half the respondents use OPA to disinfect flexible and rigid endoscopes, and transvaginal probes. Other medical devices disinfected with OPA include the following:

- Transesophageal Echocardiogram (TEE) probes;
- Anal probes;
- Transducers;
- Wires;
- Dilators;
- Catheters;
- Stylettes;
- Rectal Biopsy Tools; and,
- Water Bottles (endoscope accessory)

Length of Time to Clean a Device after Procedure

Responses vary among respondents when asked how long after a procedure devices are cleaned with OPA. The length of time varied from immediately after the procedure to one hour after the procedure. This variation may be attributed to hospital procedures related to removing the device from the clinical area and transporting it to the cleaning/disinfection area. When a device has been used in the operating room (OR), staff responsible for cleaning the device will often have to wait until the procedure ends to receive it for cleaning. To try and minimize that exposure, they begin cleaning the device as soon as it's received from the OR. All respondents say their facility has a standard operating procedure (SOP) for getting the device from the OR to the disinfection room.

Manual vs. Automatic Reprocessing

Medical device reprocessing is a set of validated processes used to render a medical device that has been previously used or contaminated, fit for a subsequent single use on another patient. These processes are designed to remove soil and contaminants by cleaning and to inactivate

microorganisms by disinfection or sterilization. Typically, manual reprocessing is completed by hand by hospital staff and automatic reprocessing is done by an automated endoscope reprocessor (AER).

A combination of both manual and automatic reprocessing methods are used by the majority of respondents because of the variety of devices at each facility. Most manually clean devices such as transvaginal probes, catheters, and stylettes due to device heat sensitivity, lack of turnover volume, cost, and space requirements.

While utilizing manual cleaning methods for some devices, that same respondent may use automatic reprocessing for others, such as endoscopes. For the few respondents who only use automated reprocessing they work mainly with rigid and flexible endoscopes. Because scope turnover may be as high as 150 per day, automated reprocessing is faster and more accurate than manual cleaning.

Disinfecting and Rinsing Process

The OPA manual disinfection process is similar across the majority of respondents' hospitals. Typically, prior to each use, the staff test the OPA effectiveness with test strips. The test strips measure the minimum effective concentration (MEC) to ensure the OPA will appropriately disinfect. The device is then checked to ensure it is free of leaks, tears, or other issues. Once those steps are complete the device is sprayed with an enzymatic cleaner such as Transeptic, wiped down and the surface is rinsed with fresh tap water. Then, the device is soaked in OPA for 12 minutes at a temperature of 68 degrees Fahrenheit or higher. Soaking is followed by three clean rinses with fresh water at one minute a piece. Usually all three soaking cylinders are changed out after each rinse. Then, depending on the device, it is hung to dry and excess moisture is removed by drying the device with a lint free towel. Once dry, the device is ready to be reused.

For automatic reprocessing, all cleaning is done by the AER. The AER rinses and soaks the devices based on parameters entered into the computer. Once the disinfecting cycle ends, alcohol is injected into the tubing and the machine flushes it out. Most AERs run at a temperature of 68 to 69 degrees Fahrenheit for 35 to 38 minutes. Some respondents also mention that they maintain records of all endoscopes that have been appropriately cleaned.

Staff Training

High-level disinfection training occurs during the orientation period for all new employees. All other staff typically receives training at least annually. Occasionally there are accompanying competency assessments as part of the annual or new staff training. Manufacturer representatives may conduct the trainings or hospital "super users" from various departments including Infection Prevention and Control and Central Sterile Processing may conduct the trainings.

Instructions for Use

All respondents think the OPA instructions for use are clear, easy to understand, and helpful to

the user. The OPA instructions for use include information on manual and automated reprocessing. However, one respondent comments that even though the instructions for use are clear, they are too cumbersome and have too many steps. Another says they would like additional clarification on the practice of "topping off." They say some OPA instructions for use don't mention "topping off," but believe the Association for the Advancement of Medical Instrumentation (AAMI) is currently updating its guidelines to discourage the practice. "Topping off" occurs when additional high-level liquid disinfectant is added to an AER or basin in an effort to extend the OPA reuse life. The practice of "topping off" may be discouraged because it does not extend the OPA reuse life, which should be determined by the first use/activation of the original solution.
Instructions for use are made available to staff in all areas where OPA is used. Staff can also access the instructions in the scope processing rooms, policy repositories, material data sheets, via the intranet, and the OPA containers themselves.

Personal Protective Equipment (PPE)

All respondents report that staff wear several pieces of personal protective equipment (PPE) when using OPA. These include:

- Protective eyewear;
- Masks and/or face shields;
- Gloves; and,
- Fluid resistant gowns.

To further minimize staff exposure to OPA, most respondents' facilities utilize the following:

- Glutaraldehyde user stations (GUS);
- Room and/or other local exhaust ventilation; and,
- Negative air room pressure.

Patient/Staff Reactions to OPA and Other Medical Device Disinfectants

In general, respondents report few patient/staff reactions that may be related to OPA or other medical device disinfectants. One respondent said that if OPA is not properly rinsed off it may turn mucous membranes a darker color. Another says that several years ago they had 1 to 2 patients undergoing gastrointestinal procedures that exhibited sensitivity to OPA after repeated exposures. After this experience, devices for affected patients were disinfected with ethylene oxide (EtO) instead of OPA. However, the respondent is unaware of any other details involved in these occurrences. Another respondent says a staff member mentioned that they thought they had sensitivity to OPA, but it was never documented. Strong fumes are also mentioned as a staff complaint by one respondent, but it's unclear if it was validated.

Few reactions to glutaraldehyde were reported. One respondent that previously used glutaraldehyde says their staff was instructed to wear glasses instead of contact lenses due to eye irritation. Another was aware of reports of staff skin rashes after working with glutaraldehyde. Another said their staff experienced respiratory issues that may have been from working with

peracetic acids. However, they are all unaware of the specifics of those past issues.

Contraindications

Most respondents report that per hospital and manufacturer recommendations, OPA should not be used to clean devices for certain patients. These include patients who have undergone repeat cystoscopies. OPA is also contraindicated in patients with bladder tumors and bladder cancer.

Additional Information about OPA

Respondents provide the following opinions and additional information about OPA disinfectant:

• Stains staff clothing;
• OPA as a safer alternative to glutaraldehyde may be a misperception. The respondent reports that OPA may have a lower vapor pressure than other disinfectants, but the occupational exposure limit is much lower than, for example, glutaraldehyde.
• Manufacturers should limit the purchase of OPA to facilities that are knowledgeable about the instructions for use. The respondent has observed community practices using OPA inappropriately on metal steel instruments that could be steam sterilized. According to the respondent, it's also likely that those community practices are not meeting the requirements for proper ventilation, PPE, storage, and rinsing. This can create an opportunity for injury to patients and employees. More education before a practice can order OPA can help them better understand the safety and health implications.

Summary

In general, respondents report few patient/staff reactions and sensitivities that may be related to repeated exposures of OPA and other medical device disinfectants like glutaraldehyde. Color change of mucous membranes, skin rash, strong fumes and eye irritation were some of the reactions/sensitivities respondents are aware of. The majority of respondents report using a combination of both manual and automated reprocessing methods at their facilities. Those who manually clean with OPA utilize similar processes. The most commonly cleaned devices with OPA include transvaginal probes, and rigid and flexible endoscopes. For those that use solely automated reprocessing, there are various types and manufacturer models of AERs used.

All respondents also utilize the same personal protective equipment while using OPA which includes gowns, gloves, eyewear, and masks. For the most part, respondents also think the instructions for use of OPA are clear, easy to understand, and helpful to the user. Instructions are kept in the areas OPA is used and can also be accessed online. Training is conducted during new staff orientation and then a minimum of annually by either hospital "super users" or the manufacturer's representatives. Most also report that they are aware of OPA contraindications for certain patient populations.

Survey Limitations

Although the findings add to FDA's knowledge of clinical experiences, and provide perspectives

about the use of OPA, the small sample size of the survey limits the findings. In view of this limitation, the respondents' perspectives may not represent the perspectives of all OPA users.

Therefore, these findings represent only one piece of information. No conclusions can be made about how OPA is used in the broader clinical environment based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary actions.

Highlighted MedSun Reports

Highlighted Reports

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during June 2014. All other reports can be searched under the 'MedSun reports' menu pane.

Device :
Type: Insufflator, Hysteroscopic
Manufacturer: STRYKER INSTRUMENTS,DIV OF STRYKER CORP
Brand: Fluidsafe Fluid Management System
Model#: 080CE 657

Problem:

Unit noted to be malfunctioning during procedure. Fluid deficit amount reported by machine noted to be inaccurate when compared to amount of fluid used. Machine alarming that fluid bag not connected when it was. Calculations done manually. Unit removed from service. Manufacturer to evaluate unit and provide report to facility.

Device 1:
Type: Laryngoscope, Rigid
Manufacturer: King Systems Corp.
Brand: King Vision Portable Video Laryngoscope Kit
Model#: KVLKIT3
Cat #: KVLKIT3

Device 2:
Type: Laryngoscope, Rigid
Manufacturer: King Systems Corp.
Brand: King Vision Portable Video Laryngoscope Kit
Model#: KVLKIT3
Cat #: KVLKIT3

Problem:
There were two device-related occurrences of the King Vision portable video laryngoscope in a three-day period. The first occurrence was that the crew member attempted to use the King Vision to intubate a patient and observed that the battery compartment cover was off. The crew member placed the cover back on and the scope would not turn on. The scope was set aside and intubation was completed with standard laryngoscope. There was no adverse outcome to the patient. Follow up: One of the three batteries had been placed in the wrong direction. Experienced staff indicated contributing factors to be poor equipment design, excessive distractions and haste. On a different day, The King Vision was found to be inoperable during the treatment of a multi-trauma patient. There was another King Vision available on a second rig that was at the scene and so that one was used to intubate the patient. The non-operational scope was pulled from service. Inspection of the device revealed that the batteries were incorrectly inserted and that is why the unit did not work. Experienced staff listed contributing factors as being a poor equipment design, excessive distraction and haste.
Further follow up: Changing batteries in the device was part of the training, but the device is not used frequently and so staff may be not recall the correct steps.
The black strip (ribbon) must be placed properly under all three batteries (3 AAA size alkaline batteries) to assure ease of removal. Staff have experienced problems with the black strip and have found that if it is just pushed down, the batteries may not make correct contact and that the bottom battery has to get dug out. Also, if the batteries are not in proper place, the cover is hard to open. It was reported that some staff are using a coin to open the compartment when it is difficult to open. Staff involved received follow up and training. This device is not new to this facility.

Device 1:
Type: Laser, Benign Prostatic Hyperplasia
Manufacturer: AMS (American Medical Systems, Inc)

Brand: Greenlight Hps Laser System
Model#: 0010-0070

Device 2 :
Type: Powered Laser Surgical Instrument
Manufacturer: AMS (American Medical Systems, Inc)
Brand: Fiber Optic Greenlight Hps Bph
Model#: 10-2090
Lot #: 10-2090-318H
Cat #: 10-2090

Device 3 :
Type: Powered Laser Surgical Instrument
Manufacturer: AMS (American Medical Systems, Inc)
Brand: Greenlight Hps Bph Fiber
Model#: 10-2090
Lot #: 10-2090-316H
Cat #: 10-2090

Problem:
Laser tested before procedure: laser ready. Laser then stopped "171" message received, ready and functioned again. Laser stopped and went into safety shutdown. Laser fiber changed: again ready. Laser again went into shutdown error "171","210", "172". Surgeon noted tip of laser fiber disintegrated, removed fiber from patient and separated tip removed from patient using flexible grasper. No additional medical intervention required once separated tip was removed.

Device 1:
Type: Set, Administration, Intravascular
Manufacturer: USA Medical
Brand: Microclave Neutral Displacement Connector
Cat #: MC100

Device 2:
Type: Set, Administration, Intravascular
Manufacturer: USA Medical
Brand: Microclave Neutral Displacement Connector
Cat #: MC100

Problem:
Patient has Mediport with a the Microclave Connector. When RN went to use it, the spiral white part which is normally inside the tip/shaft of the connector was sticking out of the connector. Connector was replaced. The following evening, the spiral portion again found pulled out. Parent reported seeing the child sticking her fingers in it. Item replaced and parafilm placed over it in attempt to keep child from getting to it. It is believed child is able to get her small fingers in the tip and tug on the white spiral piece pulling it out.

Device:
Type: Set, Administration, Intravascular
Manufacturer: Baxter Healthcare Corp.
Brand: One-link Needle-free Iv Connector With Neutral Fluid Displacement, Power Injectable
Model#: 7N8399
Cat #: 50085412091780

Problem:
This involves new Baxter One-Link Needle Free IV Connector used on IV ports and central lines. Baxter IV Connectors prevent adequate flow through PIVs and central lines. Staff have noted similar events on multiple patients.
Brought patient to CT to scan with contrast. Noted that PIV was no good because of bad flow and/or flush; technicians encountered difficulty in flushing and were unsure if contrast could be inserted at adequate pressure. When cap was removed and flushed directly at hub of PIV, PIV flushed with no resistance. Baxter connectors have a type of negative pressure (resistance) within, creating increased difficulty of rapid infusion of fluids/ blood, or even quick flush. In this case, the test could be completed without the cap and without having to restart another IV line. However, in some cases, the IV may be restarted because the provider believes that the line is not adequate, when in fact it is.

Device:
Type: Support, Patient Position
Manufacturer: SAGE Products LLC
Brand: Prevalon Turn And Position System
Cat #: 7200

Problem:
Patient went to MRI at 1300. Prior to leaving, temperature was documented at 1200 as 36.9. Upon return from MRI at 1500, temperature was documented as 39.0. Patient was on the Prevalon Turn and Position system during MRI. No apparent injury. Patient monitored. Device instructions for use do not indicate that the device cannot be used in the MRI suite. No indications regarding MRI compatability are listed on the device information sheets.

Device:
Type: System, Balloon, Intra-aortic And Control
Manufacturer: Datascope Corp.
Brand: Cardiosave
Model#: D998-00-0800-53
Other #: Hybrid

Problem:
An elderly patient had hypertension (HTN), a myocardial infarction (MI) and was in shock. The patient had major vessel occlusions and was catheterized and resuscitated, but required an intra-aortic balloon pump (IABP). The flight team was requested from our facility to pick the patient up at the outside facility and transport them back to our facility for extracorporeal membrane oxygenation (ECMO). The transport team arrived and attempted to switch the patient to the

Maquet Cardiosave hybrid IABP. The team could not get an electrocardiogram (EKG) tracing on the IABP regardless of using alternate cables, connectors, etc., and therefore, were not able to transport the patient who required an inflight EKG tracing for balloon pump management. The patient ultimately was transported by another carrier by ambulance, coded en route and was returned to the sending hospital where she died.
Manufacturer response: They could not duplicate the problem; however, they did determine that the unit displayed corrupt date and time on the log printout, and they replaced the executive processor board.

Device:
Type: Ventilator, Continuous, Facility Use
Manufacturer: GE MEDICAL SYSTEMS INFORMATION
Brand: Engstrom Carestation
Model#: RT
Other #: 9067

Problem:
Patient's ventilator stopped giving breaths suddenly with one alarm that was silenced; then there were no further alarms while it slowly counted down from set rate of 24 to 20, 16,10,9 then a flat line with no breaths being given. Despite checking all tubing being connected and vent plugged in, no breaths were given despite ventilator screen still lit. No further alarms despite no functioning by the ventilator. Performed super user calibrations and unit passes all testing. Ventilator was removed from service. The RN was in the patient's room at the time, and was able to bag the patient. Patient was not injured.

Device :
Type: Catheter, Angioplasty, Peripheral, Transluminal
Manufacturer: Boston Scientific
Lot #: 15979839
Cat #: PCB802090

Problem:
Patient underwent successful re-channeling of iliac artery stenosis on the left, but developed bleeding at the site of the 7FR sheath on her left groin. Changed to a new 7FR sheath and bleeding slowed but did not stop. The initial 7FR sheath was noted to have a split in its length when it was removed. This believed to be due to the cutting balloon. Patient required a trip to the OR for open left femoral artery repair. The laceration required two sutures.

Device:
Type: Shunt, Central Nervous System
Manufacturer: Codman and Shurtleff, Inc.
Brand: Codman Eds 3Drainage System

Problem:
On at least two occasions the base of the ventricular drainage system sampling port has cracked. This caused small amounts of CSF to leak and is an infection risk to the patient, as it is a closed

system with direct access to the patient's brain.

Device:
Type: Accelerator, Linear, Medical
Manufacturer: Varian Medical Systems, Inc.
Brand: Trilogy Delivery System
Other #: 3404

Problem:
Male patient with UT3 N1 M0 moderately differentiated invasive rectal carcinoma was undergoing adjuvant radiotherapy to treat his tumor prior to low anterior resection. Patient placed on belly board. Treated the posterior-anterior (PA), right and left lateral fields. Planned to treat the anterior-posterior (AP) field. Noticed the table had shifted from the treatment position that they had set up. Realigned the patient and treated the anterior-posterior (AP) field.

Device :
Type: Pump, Infusion
Manufacturer: Baxter Healthcare Corporation
Brand: Baxter Sigma Spectrum Infusion Pump
Model#: 35724
Cat #: 35724

Problem:
While reviewing the pump Event History Log, we noticed there were entries of the pump going into "Sleep Mode" following a downstream occlusion. We are not familiar with this mode and after calling Baxter/Sigma they too were not able to define what this mode was. We have several hundred of these pumps and never saw this.

Device:
Type: System, Surgical, Computer
Manufacturer: Intuitive Surgical, Inc
Brand: Endowrist
Cat #: 420172

Problem:
Difficulty 3x loading instrument into the second robotic arm. Once loaded, it wouldn't advance so had to be manually advanced and struck a vessel causing 500ml bleeding and vessel injury. Had to convert to open in order to control bleeding.

From staff-written description on Intuitive Surgical complaint form: The robot was docked and the resident assisting the surgeon attached* the endowrist Maryland into the second robotic arm. It did not load** properly, however, and he had difficulty reloading it so he withdrew the instrument and loaded it again. The instrument did not advance and he manually advanced the instrument, striking and injuring a vessel in the process. Estimated 500ml blood loss but bleeding was controlled even though a definitive vessel injury was not found.

*Attachment means the motion transfer wheels of the instrument are coupled to the motor-driven wheels of the arm via a cartridge.
**Load means the laparoscopic insertion of the instrument into the patient via a trocar.

Device:
Type: Heart-valve, Non-allograft
Manufacturer: Medtronic Heart Valves
Brand: Mosaic Mitral Bioprosthetic Heart Valve
Model#: 310 Cinch
Cat #: 310C29

Problem:
A Mosaic mitral valve was opened. As surgeon was loading it onto the valve holder, the valve separated from the blue carrier and we noticed the suture was broken. We opened an identical valve which was implanted without incident. The rep was notified, so he is aware of the situation. We are working on getting a replacement for our stock.

Device 1:
Type: 12 Mm Endo Gia Ultra Universal Stapler
Manufacturer: Covidien
Brand: Endo Gia Ultra Universal Stapler
Lot #: P4D0019X
Cat #: EGIAUSTND

Device 2:
Type: Reload, Staple, Implantable
Manufacturer: Covidien
Brand: Endio Gia Black Articulating Reload
Lot #: N4C0428KX
Cat #: EGIA60AXT

Problem:
The lung contained multiple nodules and the parenchyma was thickened. On coming across the lower lobe for the wedge biopsy, the Covidien stapler with 60 mm black load completely locked on the lung tissue, and the surgeon was unable to back out the blade or remove it, even with measures recommended by the Covidien representative. Another stapler was fired behind this stapler to free up the specimen, however, the tissue was so thick at that point that there was bleeding from the lung parenchyma and he decided to open and complete the lower lobe wedge resection and control the parenchymal bleeding. A sliver of the specimen was left in the staple cartridge as it was simply impossible to remove it even after the stapler was removed and trying to push back the blade manually.

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Manufacturer response for Black Articulating Reload with Tri-Staple Technology, Endio GIA Black Articulating Reload with Tri Staple Tech. (per site reporter)
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The Covidien Rep is sending us a container to return the device in. The hospital will be holding onto the device for a while. Not sure when it will be returned.

Device:
Type: Electrosurgical, Cutting &Coagulation &Accessories
Manufacturer: MAQUET Cardiovascular LLC
Brand: Vasoview Hemopro 2

Problem:
Approximately two years ago in the late fall, patient underwent coronary artery bypass graft. A vessel was harvested from the right leg and used successfully in the graft. Approximately 16 months later, in the spring, the patient experienced itching and discomfort in her right calf. The patient experienced discomfort that she described as 'like a splinter' and discovered a small splinter-object protruding from her calf. The patient used a pair of tweezers to remove the object and removed a piece of tubing approximately 4" long from her calf.
The patient presented to the surgeon for follow up care approximately 4 days later. No other issues were noted.
Originally, the patient kept the piece of tubing and did not turn it over to the hospital for investigation. The hospital received the tubing two months later.